

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA :
ex rel SUSAN MULCAHY :
8 Common Street, Unit 4 :
Stoneham, MA 02180, :

DOREEN MERRIAM :
23 Sylvan Place :
Longmeadow, MA 01106 :

SONDRA KNOWLES :
16 Coachman Ridge Road :
Shrewsbury, MA 01545 :

Plaintiffs/Relators, :

v. :

ABBOTT LABORATORIES & :
ABBOTT PHARMACEUTICALS :
PR LTD. :

Defendants. :

CIVIL ACTION NO.

FILED
UNDER SEAL

JURY TRIAL DEMANDED

SEALED

QUI TAM COMPLAINT

Plaintiffs/Relators, Susan Mulcahy, Doreen Merriam and Sondra Knowles (collectively, "Relators"), by their attorney, for their complaint against Defendants Abbott Laboratories, Inc. and Abbott Pharmaceuticals PR Ltd., allege the following:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false statements and claims presented, or caused to be presented, by the Defendants to the United States, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729-32, as amended (the "FCS").

2. Pursuant to 31 U.S.C. § 3730(b)(2) of what is commonly known as the False Claims Act, this Complaint is to remain under seal for at least 60 days and is not to be served on Defendants until the Court so orders.

3. As required by 31 U.S.C. § 3730(b)(2), immediately upon filing of this Complaint, Plaintiffs/Relators will serve the United States of America ("United States") with a copy of this Complaint and a written disclosure. The United States may elect to intervene and proceed with this action within 60 days after it receives the Complaint and written disclosure.

4. This lawsuit stems from Defendants' off-label uses of three medications: Depakote, Depakote ER, and Depakote Sprinkles (collectively, "the Depakote Drugs").

5. Relators Susan Mulcahy, Doreen Merriam, and Sondra Knowles all are residents of the Commonwealth of Massachusetts. Relator Susan Mulcahy is currently a specialty account executive with Abbott Laboratories. Relator Doreen Merriam is also employed by Abbott Laboratories and is a specialty account executive. Relator Sondra Knowles was employed by Abbott Laboratories from 2001 to 2007. Relators are the original source of the facts and information hereinafter set forth concerning the activities of the Defendants. The facts averred herein are based entirely upon their personal observation and documents in their possession.

6. Defendant Abbott Laboratories is described on its website as "a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health." It is incorporated in the state of Illinois with its principal place of business and headquarters at Abbott Park, Illinois 60064. Abbott Laboratories develops,

manufactures, licenses and markets pharmaceutical products including prescription drugs falling under the jurisdiction and regulation of the United States Food and Drug Administration.

7. Defendant Abbott Pharmaceuticals PR Ltd. is a subsidiary of Abbott Laboratories organized in Bermuda and located in Barceloneta, Puerto Rico.

8. According to the Physician's Desk Reference, both Depakote and Depakote ER are manufactured by Defendant Abbott Pharmaceuticals PR Ltd. for Abbott Laboratories. Upon information and belief, Depakote Sprinkles are manufactured in Illinois for Abbott Laboratories.

JURISDICTION AND VENUE

9. The Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730.

10. This Court has jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because defendants can be found and have transacted the business that is the subject matter of this lawsuit in the District of Columbia.

11. Venue is proper pursuant to 31 U.S.C. § 3732(a) in that Defendants can be found, reside in and have transacted the business that is the subject matter of this lawsuit in the District of Columbia.

FACTS

12. Relators have prepared, and will provide with this Complaint to the Attorney General of the United States and the United States Attorney for the District of Columbia, a disclosure pursuant to 31 U.S.C. § 3730(b)(2) of material evidence and information in their possession related to the Complaint and of which they are the original source. This disclosure supports the existence of the claims being filed or presented herein.

13. The United States Food & Drug Administration (the “FDA”) is entrusted by law, 21 U.S.C. §§ 301 et seq., with the responsibility to ensure, among other things, that the American public is treated medically only with drugs that have met certain standards with respect to efficacy and safety and that are appropriately labeled.

14. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as “off-label” uses. Pursuant to its rulemaking authority, the FDA has promulgated regulations that restrict the marketing efforts that a pharmaceutical company can make with respect to potential uses of its drugs over and above those uses of that product which have been specifically approved by the FDA. 21 C.F.R. § 99.1 et. seq.

15. The FDA regulations provide that “a manufacturer may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling for an approved drug...provided that the manufacturer complies with all other relevant requirements under this part.” Among the requirements are: (1) that the drug has been approved, licensed or cleared for marketing by the FDA for some purpose; (2) that the communications by the manufacturer be in the form of research published in a scientific or medical journal; (3) that the communications not be false or misleading or incomplete; (4) that

the communications disclose if the information is being disseminated at the expense of the manufacturer; (5) that the communications disclose if any of the authors were paid by the manufacturer; (6) that the communications identify any person paying for studies; (7) that the drug not pose a significant threat to public health; and (8) that it be labeled as information concerning a use that has not been approved by the FDA. 21 C.F.R. § 99.101-99.103.

16. Among Abbott Laboratories' products are the Depakote Drugs (divalproex sodium), which are aimed at aimed at treating the symptoms of persons with bipolar disorder and seizures as a result of epilepsy.

17. In 1983, Defendant Abbott Laboratories received permission from the FDA to market Depakote to physicians and other medical care providers for the purpose of treating manic episodes associated with bipolar disorder and for the purpose of treating complex partial seizures for persons suffering from epilepsy. In 1989, Defendant Abbott Laboratories received permission from the FDA to market Depakote Sprinkles to treat seizure disorders. In 2002, the FDA approved Depakote ER (extended-release) for the treatment of acute manic or mixed episodes associated with bipolar disorder and for the treatment of complex partial seizures for those suffering from epilepsy. Both Depakote and Depakote ER have also been approved for the prevention of migraine headaches in adults. The FDA has not approved the Depakote Drugs for any other use than those listed in this paragraph.

18. Abbott Laboratories' total sales of Depakote in 2006 were approximately \$1.2 billion and its total sales of Depakote ER in 2001 was approximately \$500 million.

19. The practice of advocating the use of a drug to treat conditions not specifically approved by the FDA is called "off-label marketing." Unless performed in

accordance with the FDA regulations described in paragraph 14 above, it is illegal when engaged in by drug companies, but not illegal when engaged in by independent physicians based on their own independent medical judgment.

20. After obtaining FDA approval of the Depakote Drugs, Defendants formed a scheme to increase the sales of the drugs while avoiding the substantial expense and delay of petitioning the FDA for approval of expanded or additional uses of the drugs. The scheme consisted of an elaborate and clandestine promotion of off-label uses of the drugs, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency.

21. In particular, Defendants promoted the following off-label uses of the Depakote Drugs: for treating dementia and for behaviors seen in Alzheimer's patients.

22. Upon information and belief, between approximately 2001 and at least 2007, Defendants have, passively and explicitly, encouraged physicians and medical providers to bill Medicare and other government reimbursement programs for the Depakote Drugs for "off-label" uses, and to represent thereby that the off-label use for which reimbursement is being requested was the result of the medical providers' independent and impartial medical judgment. Defendants did this while knowing that they were, in fact, surreptitiously advocating the use of the Depakote Drugs for off-label purposes through means other than those approved by FDA in its regulations and that these means were designed to evade the Defendants' responsibility to present a balanced view of the Depakote Drugs, their risks and benefits.

23. Among the methods by which Defendants accomplished the foregoing means were the following:

- (a) Defendants provided sales aids and materials to their sales representatives that required them to encourage nursing facilities to use the Depakote Drugs off-label;
- (b) Defendants exerted significant pressure on their sales representatives, including Relators, to increase off-label uses of the Depakote Drugs by all possible means and provided skewed incentives for such use;
- (c) Defendants devised and conducted "Selling Skills Workshops" for all of its sales representatives devoted to non-label uses;
- (d) Defendants disguised the subject matter of "seminars" for physicians by assigning general titles to speeches that, in fact, were exclusively devoted to off-label uses;
- (e) Defendants offered sales representatives incentives and bonuses for promoting off-label uses of the Depakote Drugs;
- (f) Defendants illegally directly solicited physicians to use the Depakote Drugs for off-label uses;
- (g) Defendants failed to disclose that favorable articles were written by physicians paid, directly or indirectly, by Defendants;
- (h) Defendants made false statements to physicians, nursing homes, and nursing facilities concerning the efficacy and safety of the Depakote Drugs for off-label uses;
- (i) Upon information and belief, Defendants' sales department paid kickbacks to physicians which were frequently disguised. The kickbacks have taken the form of honoraria and other benefits. Defendants have targeted physicians for the award of these benefits based in large part on the number of off-label prescriptions written by or likely to be written by the physicians or the ability of the physician to influence other physicians to begin prescribing the Depakote Drugs for off-label uses; and

(j) Defendants actively trained their employees, including Relators, in methods of avoiding detection of their illegal activities by the FDA. Defendants stated their goal was to avoid detection by the FDA.

24. The Medicare and Medicaid Fraud and Abuse Statute was first enacted under the Social Security Act in 1977. The statute imposes criminal penalties on whomever violates the Anti-Kickback Provision and

offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(B). This statute prohibits the mere act of offering such illegal remuneration, regardless of whether the inducement is ultimately accepted by the buyer. Such inducements are harmful to the federal government because they encourage unnecessary treatments, influence the free exercise of medical judgment by providers, limit patient options and lead to higher federal payments for medical services.

COUNT I
DELIBERATE AVOIDANCE OF FDA REGULATIONS/
MEDICARE AND MEDICAID FINANCED SALES – THE DEPAKOTE DRUGS

25. Relators reallege and incorporate by reference herein the allegations contained in paragraphs 1 - 24 above.

26. A significant percentage of patients who use or who have used the Depakote Drugs for off-label purposes are persons who are over the age of 65 whose

prescriptions are paid for, in whole or in part, by state administered medical assistance programs which receive 90% reimbursement from the federal government, to wit, Medicare and Medicaid.

27. The Medicare and Medicaid programs of the federal government include detailed provisions, by statute and regulation, concerning reimbursement for prescription drugs, drug utilization review, eligibility of various drugs for full federal participation price controls on prescription drugs, and drug manufacturer rebate agreements. These laws and regulations include, inter alia, as set forth as 42 U.S.C. § 1395y(c), that no federal payment shall be made in the case of a prescription drug for which the FDA has issued a notice of hearing regarding the effectiveness of the drug. Thus, the taking of a regulatory action by the FDA against the sale and promotion of a drug will, in circumstances, immediately interrupt the flow of federal funds for reimbursements of prescriptions written for the drug.

28. Promotion of off-label usage of a drug constitutes "labeling" as defined by the food and drug laws of the United States. It is reasonably certain, and Defendants are aware, that if the FDA became aware of its extensive program of illegal promotion of off-label uses of the Depakote Drugs, the FDA would take administrative action against Defendants, including, among other things, a notice of hearing regarding the effectiveness of the Depakote Drugs for the promoted off-label uses. Such a notice would, by federal statute, instantly interrupt the flow of federal funds for reimbursement for off-label prescriptions.

29. Defendants have, as alleged, actively concealed their off-label promotion of the Depakote Drugs from the FDA with specific training to Defendants' employees to do so. Said active concealment is motivated by the desire to, and has had the effect of, preserving the flow of federal funds to reimburse the Depakote Drugs prescriptions. Said active concealment

constitutes a pattern of fraudulent conduct through which federal payments are derived, and constitutes False Claims within the meaning of 31 U.S.C. § 3729.

COUNT II
FALSE STATEMENTS TO PHYSICIANS – THE DEPAKOTE DRUGS

30. Relators reallege and incorporate by reference herein the allegations contained in paragraphs 1 - 29 above.

31. As part of their illegal off-label promotions of the Depakote Drugs, Defendants have instructed and caused their sales personnel and their medical employees to make false statements to physicians, deliberately omit material information to physicians, and to brief physicians based upon written materials containing false statements and omissions, concerning the safety and efficacy of the Depakote Drugs for off-label uses. These statements were made with the intent of, and had the effect of, inducing physicians to increase their off-label prescriptions of the Depakote Drugs. This increased off-label prescription of the Depakote Drugs caused harm to the federal government by increasing the number of Medicare and Medicaid claims for prescriptions of the Depakote Drugs.

32. Defendants' false statements and deliberate omissions of material information to physicians were a pattern of fraud designed to induce payments by the federal government, and constituted a violation of the FCS within the meaning of 31 U.S.C. § 3729.

COUNT III
ILLEGAL KICKBACKS – THE DEPAKOTE DRUGS

33. Relators reallege and incorporate by reference herein the allegations contained in paragraphs 1 - 32 above.

34. Federal laws and regulations governing the Medicare and Medicaid programs prohibit kick-backs to physicians and medical care providers, in particular 42 U.S.C. § 1320a-7a (civil penalties), 42 U.S.C. § 1320a-7b (criminal penalties) and 42 C.F.R. § 1003.100 et. seq. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

35. As part of their nationwide program of off-label promotion of the Depakote Drugs, Defendants have established a system of kick-backs to physicians who prescribe large amounts of the Depakote Drugs as described in paragraph 23 and its subparts.

36. These kick-backs are strictly illegal and have had the effect of greatly increasing the amount of prescriptions of the Depakote Drugs, and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by Medicare and Medicaid. The payment of these kick-backs represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT IV
DIRECT SALES TO VETERANS ADMINISTRATION – THE DEPAKOTE DRUGS

37. Relators reallege and incorporate by reference herein the allegations contained in paragraphs 1 - 36 above.

38. Defendants have sold, and are selling, significant quantities of the Depakote Drugs to the Veterans Administration for off-label uses.

39. Defendants are conducting, and have conducted, illegal direct promotion of off-label uses of the Depakote Drugs directly to the Veterans Administration. Defendants

have, on a nationwide basis, illegally and directly promoted off-label uses of the Depakote Drugs to Veterans Administration physicians and pharmacists. These illegal promotional activities have resulted in greatly increased use of the Depakote Drugs by the Veterans Administration. Defendants' sales to the Veterans Administration have been derived through a pattern of fraud, to wit, the deliberate violation of the laws and regulations of the United States and the deliberate active concealment of those violations. Defendants' deliberate violation of federal law used as a method of procuring sales of drugs to an agency of the federal government constituted a False Claim within the meaning of 31 U.S.C. § 3729.

40. Defendants' medical, sales and marketing personnel have promoted the off-label use of the Depakote Drugs by the Veterans Administration by deliberate omissions of material information and making false and unfounded claims to Veterans Administration physicians and pharmacists concerning the safety and efficacy of the Depakote Drugs for off-label uses. These claims of safety and efficacy for off-label uses are false and made with reckless disregard of the truth or deliberately omit material information. Defendants' use of false statements concerning the safety and efficacy of the Depakote Drugs used as a means of procuring sales to the Veterans Administration constituted False Claims within the meaning of 31 U.S.C. § 3729.

COUNT V
VIOLATING STATE FORMULARIES/
MEDICARE AND MEDICAID - THE DEPAKOTE DRUGS

41. Relators reallege and incorporate by reference herein the allegations contained in paragraphs 1 – 40 above.

42. Under the statutes and regulations establishing the Medicare and Medicaid programs, the individual states are permitted to establish drug utilization review boards and formularies which define those prescription drugs and their uses for which a state agency will make reimbursement under their Medicare programs. Federal law, in particular 42 U.S.C. § 1396r-8, requires a state formulary to include medically accepted uses of prescription drugs by reference to the publications set forth, in paragraph 14, supra.

43. Many state Medicare agencies intend not to reimburse for prescription drugs for uses not set forth in the publications referred to in paragraph 15, supra, in that the states do not intend to spend money on prescriptions not recognized as medically necessary in sources specified by federal law. However, many states lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted according to the federally specified publications. This lack of technical ability represents a loop-hole in the structure of the Medicare and Medicaid programs.

44. Defendants have recognized and aggressively exploited this loop-hole by means of a direct, illegal, nationwide program of promotion of off-label use of the Depakote Drugs by physicians. Defendants have conducted this program of promotion knowing that prescriptions for the Depakote Drugs are generally reimbursed by state Medicare programs even though individual prescriptions for the Depakote Drugs fall outside of state formularies because they are not medically proven through the conducting of unbiased trials.

45. Defendants' aggressive, illegal scheme of off-label promotion has induced federal payments through a pattern of fraudulent conduct by causing the states, and thus the

federal government, to pay out sums to claimants they did not intend to benefit. Defendants' conduct constitutes a violation of the FCS within the meaning of 31 U.S.C. 3729

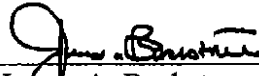
WHEREFORE, Relators demand judgment in their favor and against Defendants as follows:

(a) For an amount equal to three times the amount of damages the United States has sustained because of each Defendant's actions, plus a civil penalty of not less than \$5,000.00 nor more than \$10,000.00 for each violation of 31 U. S. C. § 3729;

(b) For a judgment in favor of Relators, as Qui Tam Plaintiffs, in the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of law;

(c) For a judgment in favor of Relators, as Qui Tam Plaintiffs, for all costs of this action, including, but not limited to, attorneys' fees, expert fees, and court costs; and

(d) For a judgment in favor of Relators, as Qui Tam Plaintiffs, for such other and further relief as the Court deems just and proper.



James A. Backstrom (D.C. Bar I.D. 924274)
2 Penn Center, Suite 200
Philadelphia, Pennsylvania 19102-1706
Telephone 215-864-7797

Counsel for Plaintiffs/Relators

DATED: December 12, 2007

CIVIL COVER SHEET

JS-44
(Rev. 1/05 DC)

I (a) PLAINTIFFS SUSAN MULCAHY, DOREEN MERRIAM, & SONDR A KNOWLES	DEFENDANTS ABBOTT LABORATORIES & ABBOTT PHARMACEUTICALS PR LTD.
(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF <u>88888</u> (EXCEPT IN U.S. PLAINTIFF CASES)	COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT <u>88888</u> (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED
(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER) JAMES A. BACKSTROM 2 Penn Center, Suite 200 Philadelphia, Pennsylvania 19102-1706 Telephone 215-864-7797	ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION (PLACE AN x IN ONE BOX ONLY)	III CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) <u>FOR DIVERSITY CASES ONLY!</u>																								
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="radio"/> 1 U.S. Government Plaintiff </div> <div style="width: 45%;"> <input checked="" type="radio"/> 3 Federal Question (U.S. Government Not a Party) </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <input type="radio"/> 2 U.S. Government Defendant </div> <div style="width: 45%;"> <input type="radio"/> 4 Diversity (Indicate Citizenship of Parties in item III) </div> </div>	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> </tr> </thead> <tbody> <tr> <td>Citizen of this State</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td>Incorporated or Principal Place of Business in This State</td> <td style="text-align: center;"><input type="radio"/> 4</td> <td style="text-align: center;"><input type="radio"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td style="text-align: center;"><input type="radio"/> 5</td> <td style="text-align: center;"><input type="radio"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="radio"/> 6</td> <td style="text-align: center;"><input type="radio"/> 6</td> </tr> </tbody> </table>		PTF	DFT		PTF	DFT	Citizen of this State	<input type="radio"/> 1	<input type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4	Citizen of Another State	<input type="radio"/> 2	<input type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5	Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6
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IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place a X in one category, A-N, that best represents your cause of action and one in a corresponding Nature of Suit)

<input type="radio"/> A. Antitrust <input type="checkbox"/> 410 Antitrust	<input type="radio"/> B. Personal Injury/Malpractice <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Medical Malpractice <input type="checkbox"/> 365 Product Liability <input type="checkbox"/> 368 Asbestos Product Liability	<input type="radio"/> C. Administrative Agency Review <input type="checkbox"/> 151 Medicare Act <u>Social Security:</u> <input type="checkbox"/> 861 HIA ((1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g) <u>Other Statutes</u> <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 890 Other Statutory Actions (If Administrative Agency is Involved)	<input type="radio"/> D. Temporary Restraining Order/Preliminary Injunction Any nature of suit from any category may be selected for this category of case assignment. *(If Antitrust, then A governs)*
<input checked="" type="radio"/> E. General Civil (Other) OR <input type="radio"/> F. Pro Se General Civil			
<u>Real Property</u> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent, Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property <u>Personal Property</u> <input checked="" type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<u>Bankruptcy</u> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <u>Prisoner Petitions</u> <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <u>Property Rights</u> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <u>Federal Tax Suits</u> <input type="checkbox"/> 870 Taxes (US plaintiff or defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609	<u>Forfeiture/Penalty</u> <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 RR & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <u>Other Statutes</u> <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 430 Banks & Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation	<input type="checkbox"/> 470 Racketeer Influenced & Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Satellite TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 900 Appeal of fee determination under equal access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

<input type="radio"/> G. Habeas Corpus/ 2255 <input type="checkbox"/> 530 Habeas Corpus-General <input type="checkbox"/> 510 Motion/Vacate Sentence	<input type="radio"/> H. Employment Discrimination <input type="checkbox"/> 442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	<input type="radio"/> I. FOIA/PRIVACY ACT <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 890 Other Statutory Actions (If Privacy Act) *(If pro se, select this deck)*	<input type="radio"/> J. Student Loan <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (excluding veterans)
<input type="radio"/> K. Labor/ERISA (non-employment) <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Labor Railway Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="radio"/> L. Other Civil Rights (non-employment) <input type="checkbox"/> 441 Voting (If not Voting Rights Act) <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 American w/Disabilities-Employment <input type="checkbox"/> 446 Americans w/Disabilities-Other	<input type="radio"/> M. Contract <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholder's Suits <input type="checkbox"/> 190 Other Contracts <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="radio"/> N. Three-Judge Court <input type="checkbox"/> 441 Civil Rights-Voting (If Voting Rights Act)

V. ORIGIN

- ☒ 1 Original Proceeding
 ☐ 2 Removed from State Court
 ☐ 3 Remanded from Appellate Court
 ☐ 4 Reinstated or Reopened
 ☐ 5 Transferred from another district (specify)
 ☐ 6 Multi district Litigation
 ☐ 7 Appeal to District Judge from Mag. Judge

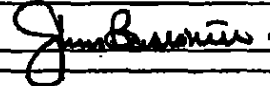
VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE).
 Qui Tam Federal False Claims Act, 31 U.S.C. Sections 3729-32, Lawsuit against drug makers for off-label marketing and sales of prescription drugs.

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND \$** _____ **JURY DEMAND:** YES ☒ NO ☐ Check YES only if demanded in complaint

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO ☒ If yes, please complete related case form.

DATE 12/12/07

SIGNATURE OF ATTORNEY OF RECORD



INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the Cover Sheet.

- I.** COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff is resident of Washington, D.C.; 88888 if plaintiff is resident of the United States but not of Washington, D.C., and 99999 if plaintiff is outside the United States.
- III.** CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV.** CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of case.
- VI.** CAUSE OF ACTION: Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII.** RELATED CASES, IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.